REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

By way of this amendment, claims 1-20 are pending. Claims 1-20 have been amended to remove the terms "inhibiting" and "preventing." Accordingly, no questions of new matter should arise and entry of this amendment is respectfully requested.

Rejection of claims 1-6, 8, 10, 11, 19, and 20 under 35 U.S.C. §102(b) – Powers et al.

At page 2 of the Office Action, the Examiner rejects claims 1-6, 8, 10, 11, 19, and 20 under 35 U.S.C. §102(b) as being anticipated by Powers et al. (U.S. Patent No. 5,543,396). The Examiner asserts that Powers et al. teaches a pharmaceutical composition in any form comprising the elected compound, and the Examiner makes reference to the "tissue remodeling" at col. 1, lines 41-43 of Powers et al. and appears to equate this "tissue remodeling" to include tissue adhesion formation. The rejection in its entirety is respectfully traversed.

Claim 1 of the present application recites a medicament for treating adhesion formation, which contains at least one protease inhibitor and is administered intravenously, orally, or percutaneously. Claim 10 recites the presence of a pharmaceutically acceptable diluent or excipient. Claim 9 further comprises a transmitter, which maintains an effective local concentration of the protease inhibitor at the relevant site. In addition, the claimed invention relates to a method for treating adhesion formation using the medicament of claim 1.

Unlike the present invention, Powers et al., while relating to a pharmaceutical composition and mentioning the inhibitor of a chymase, does not teach or suggest the pharmaceutical activities of reducing or treating adhesion formation with the use of this composition. With respect to the

claims, Powers et al. does not show a medicament for prevention or treatment of adhesion formation. Contrary to the Examiner's assertions in the Office Action, tissue adhesion formation is quite different from tissue remodeling. The applicant traverses the Examiner's position on this matter. Powers et al. does not teach or suggest that tissue remodeling encompasses tissue adhesion formation, and one skilled in the art would readily recognize the difference between tissue remodeling and tissue adhesion formation. Tissue remodeling generally involves the remodeling or rebuilding of damaged tissue, which, many times, is carried out through changing the formation of the tissue itself. For example, in bone tissue remodeling, remodeling can be done with the use of calcium metabolism and can be regulated through the balance of biosynthesis and degradation of ECM by osteoblasts and osteoclasts, respectively.

As indicated in the present application, adhesion formation many times occurs through surgical procedures, wherein the adhesion can result from a wound healing response. As described at the bottom of page 1 and page 2 of the present application, adhesion formation and adhesion-free re-epithelialization are alternative pathways, both of which begin with coagulation and which can result in the build-up of fibrin gel matrix, and if this fibrin deposition is in excess or not removed, the gel matrix serves as a progenitor to adhesions by forming a band or bridge when two tissue surfaces coated with fibrin matrix are apposed. This is quite different from tissue remodeling.

Accordingly, this rejection should be withdrawn.

Rejection of claims 1-20 under 35 U.S.C. §103(a) over Powers et al. in view of Scharpe et al.

At page 3 of the Office Action, the Examiner rejects claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over Powers et al. in view of Scharpe et al. (U.S. Patent Application Publication No. 2002/0061839 A1). The Examiner relies on Powers et al. as described above in the §102

rejection. The Examiner does acknowledge in this rejection that Powers et al. does not expressly teach the use of the elected peptide to reduce adhesion formation or the various forms of administration set forth in the claims. The Examiner relies on Scharpe et al. to assert that Scharpe et al. uses serine protease inhibitors in virtually any pharmaceutical mixture/formulation. This rejection in its entirety is respectfully traversed.

At page 3 of the Office Action, the Examiner refers to claims 25-30 of the present application to partially explain the rejection. However, only claims 1-20 are pending in this application. Clarification on the part of the Examiner is respectfully requested.

With respect to this §103 rejection, the points regarding Powers et al. above apply equally here. Powers et al. does not teach or suggest a medicament or method of using a protease inhibitor to reduce adhesion formation. As indicated above, Powers et al. makes reference to tissue remodeling, but tissue remodeling is not equivalent or a genus of treating adhesion formation as indicated above. The primary purpose of Powers et al. is to use certain derivatives as anti-coagulants, anti-inflammatory agents, and anti-tumor agents. As indicated, while there is a mention of tissue remodeling and topical applications, tissue remodeling is quite different from the reduction of adhesion formation of tissue as indicated above.

Furthermore, with respect to claim 9 (and similar claims), there is no teaching or even a suggestion in Powers et al. regarding the presence of a delivery vehicle which can maintain an effective local concentration at the site. Powers et al. merely describes a tablet or aqueous or oily suspension which would not be a teaching or a suggestion of a delivery vehicle which can maintain an effective local concentration of the protease inhibitor at the site for a period of time sufficient to reduce adhesion formation.

Furthermore, Scharpe et al. does not overcome the deficiencies of Powers et al. Scharpe et

al. does not teach or suggest treating adhesion formation.

It is important to note that in reducing or treating adhesion formation, the protease inhibitor is typically placed at the site where surgery occurs, for instance, as recited in claim 12 of the present application. Neither Powers et al. nor Scharpe et al. have any teaching or even a suggestion of providing a local concentration of a protease inhibitor at a site to reduce adhesion formation. Furthermore, with respect to, for instance, claim 11, Powers et al. and Scharpe et al. do not teach or suggest a method to treat adhesion formation by administering the medicament to a subject before, during, or after a surgical operation. Clearly, Powers et al. does not relate to the use of such medicaments in surgical operations and merely refers to anti-inflammatory, anti-coagulants, and anti-tumor uses, but makes no teaching or suggestion for purposes of treating adhesion formation in connection with a surgical operation. Further, Scharpe et al. does not at all overcome these deficiencies.

Further, it is unclear whether one skilled in the art would even look to Scharpe et al. to modify the compound of Powers et al. when Powers et al. makes no teaching or suggestion to make such a modification and, further, the particular administration routes set forth in Powers et al. are very clear with respect to use of the derivatives of Powers et al. as anti-coagulants, anti-inflammatory agents, and anti-tumor agents.

The applicant would appreciate discussing this matter with the Examiner by telephone should the Examiner have any questions regarding the differences between the uses set forth in Powers et al. and the particular product and methods claimed in the present application.

Accordingly, this rejection should be withdrawn.

Provisional Rejection – Obviousness-Type Double Patenting

At page 5 of the Office Action, the Examiner provisionally rejects claims 1-20 on the ground of obviousness-type double patenting as being unpatentable over claims 1-7, 10, 11, 12, 30, and 33 of co-pending U.S. Patent Application No. 10/602,035. This provisional rejection is respectfully traversed.

Since this is a provisional rejection, once the remaining rejections described above have been overcome, this provisional rejection may be withdrawn depending on the status and claims pending in the co-pending application.

The applicant does note that the present application relates to administering a protease inhibitor intravenously, orally, or percutaneously. These modes of administration are not recited in the claims of co-pending U.S. Patent Application No. 10/602,035.

Accordingly, this provisional rejection should be withdrawn.

Rejection of claims 1-20 under 35 U.S.C. §112, first paragraph

At page 6 of the Office Action, the Examiner rejects claims 1-20 under 35 U.S.C. §112, first paragraph, for enablement reasons. The Examiner believes that reference to "preventing" adhesion formation is not enabled by the present application. This rejection is respectfully traversed.

Applicant believes that the application is enabling for the scope provided in the pending claims. To assist the Examiner, the claims have been amended to remove reference to "preventing" since a medicament and method for reducing adhesion formation will embrace the same scope. Further, the present application teaches that the present application relates to treating adhesion formation.

Accordingly, this rejection should be withdrawn.

Rejection of claims 6-8 under 35 U.S.C. §112, second paragraph

At page 7 of the Office Action, the Examiner rejects claims 6-8 for indefinite reasons. The Examiner asserts that the phrase "L form" in the claims and specifically as used in claim 8, is not defined and, therefore, would mean the same chymase inhibitor as recited in claim 6. This rejection is respectfully traversed.

The applicants believe that the term "L-Phe" is defined in the present application, since the present application teaches, for instance at the bottom of page 17 and top of page 18, that the designation "L" is employed to designate the sign of rotation of a plane-polarized light by the compound and that the "L meaning" refers to a compound that is levorotarory. Therefore, the applicants believe that one skilled in the art reading the claims and specifically claims 7 and 8 would understand the term as used in the claims. For these reasons, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

U.S. Patent Application No. 10/544,254
Amendment dated April 10, 2007
Reply to Office Action of January 12, 2007

Respectfully submitted,

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